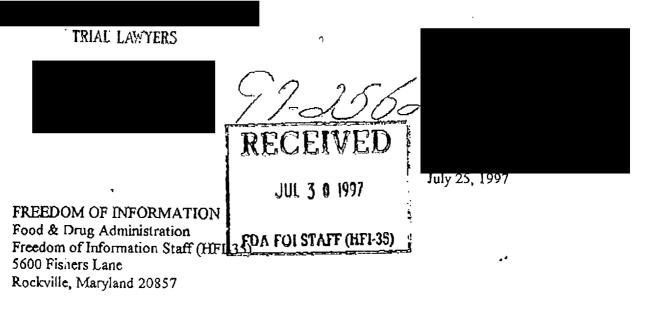
Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Special Nutritionals

ARMS#

12485



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Re:

Freedom of Information Act Request and Product Complaint

Product Name:

"Ripped Fuel" (MaHuang/Ephedrine)

Complaint:

Ingestion Resulting in Death (Fatal Arrhythmia/30 Y/O Male)

Dear Sir or Madam:

The purpose of this letter is to lodge a complaint with the YDA regarding the product known as "Ripped Fuel" manufactured by Twin Labs of N.Y., which contains "MaHuang extract" (Ephedrine) and "Guarana extract" (Caffeine) and is marketed as a metabolism enhancer and fat burner.

This firm has been retained by the widow and surviving minor daughter of the late who died of a sudden and fatal cardiac arrhythmia after ingesting the subject product and returning from jogging.

Enclosed please find a copy of the initial coroner's report and the supplemental report done at the request of decedent's physician (after he had reviewed the initial coroner's report and was perplexed as to its findings).

Upon further inquiry to the decedent's widow, Dr. discovered the decedent's use of the product known as "Ripped Fuel" and that it contained extract from the Chinese Herb known as MaHuang (ephedrine). It was at that point, Dr. requested further investigation by the coroner which resulted in the attached supplemental report.

Based thereon, Dr. success firmly of the opinion that the subject product was the medical cause of Mr. sudden and untimely death and has agreed to so testify, if necessary.

Therefore, please accept this letter as a formal complaint by Mrs. relative to this product.

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Exhibit # 6 Page 5 of 5 CFSAN Project #1285 Nianna M. Capalia, Investigator Los Angeles District - Irvine

FREEDOM OF INFORMATION July 25, 1997 Page 2

Further, please also accept this letter as a request under the Freedom of Information Act for copies of any information or investigative materials derived from investigations conducted by the FDA, to date, regarding this product.

Please also be advised that we have retained and have in our possession all of the "Ripped Fuel" capsules in their original container which remained after the decedent took his last dosage the morning of his untimely death.

We are interested in having a random sampling of these remaining capsules analyzed to determine their actual chemical content and actual concentration of ephedrine, caffeine and/or other relevant ingredients.

If the FDA conducts such testing and analysis as part of its public functions or investigations, please advise as we would like to have the FDA conduct such analysis/testing as soon as possible.

Finally, we have filed a civil wrongful death action against Twin Labs and others involved in the chain of production and distribution of the subject product; A copy of which (First Amended Complaint) is enclosed for the FDA's information.

Thank you for the FDA's attention and anticipated response to this product complaint and request for information, both of which are of grave concern to the widow and surviving minor daughter of the late



Enclosures

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Rec CRRS 8/18/97

Adverse Reaction Questionnaire

Complaint Number: CFSAN Project #12485

Investigator: Nianna M. Capalia

Consumer Information Initial Report Source: ORA Consumer Injury Date of Report: 8/27/97 Telephone Correspondence MedWatch QUSP QPQRS Poison Control QCDC OF MQ_X Age: Gender: Name: 03-Asian/Pacific Islander 04-Native American □5-Hispanic Race: 101-White Q9-Unknown □8-Other Information on Adverse Reaction Date of Adverse Reaction: 6/6/96 Give the site of consumption/ingestion (e.g. home, restaurant, office): Previous Reaction to Product Type: "Yes ⊠No. Home The following information relates to the consumers' use of the product. Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): (Please see attached sheet) How long did the symptoms last? Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.). (Please see attached sheet) List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: (Please see attached sheet) Did event abate after use of suspected product stopped or dose reduced: UYes UNo XiUnknown Did symptoms reoccur after reintroduction of suspected product: "Yes ONo CUnknown DNot Applicable Did symptoms reoccur after using other products with the same ingredients: DYes DNo NUnknown DNot Applicable Medical Information Was a health care provider seen?: HYes UNo Give health care provider's name, address and telephone number: (Please see attached sheet) **OPharmacist** DOsleopath □ Naturopath Occupation of Health Care Provider: AMD DOther (specify) (Please see attached sheet for What medical tests were performed and what were the results? this section) What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)? Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): TYes DNo (Please see attached sheet)

	Product Category
	seculal mineral; a protein; a herb or similar nutritional substances including botamicals such as general and yournes, sauce or; fish ells; oil of svening primress; fibers such as psyllium and guar gum; compounds not generally recognized as food or parlurs, nucleic soids, para-amino-bossoic soid, and ratin; and mixtures of these lagrodients.)
Other Product Problems Description Object (specify):	
Other (specify):	
Iı	nformation on Suspected/Alleged Product
Sive the product name as listed on the nd indications for use as listed on the	e label (including the recommended dosage/serving size, recommended duration of use, a label):
(Please see attached	
f a particular ingredient is suspected	of contributing to the reaction, please indicate the appropriate category below:
If a particular ingredient is suspected OAspartame OMonosodium Glutamate	
□Aspartame □Monosodium Glutamate	of contributing to the reaction, please indicate the appropriate category below:
DAspartame DMonosodium Glutamate DSulfite DOther MaHuang Extrac DUnknown Is the product label available, if yes Product Sample Available: 20Yes	of contributing to the reaction, please indicate the appropriate category below: Color Additive (please specify) t (Please see attached sheet) submit a quality copy along with this questionnaire: XDYes DNo DUnknown
DAspartame DMonosodium Glutamate DSulfite DOther MaHuang Extrac DUnknown Is the product label available, if yes Product Sample Available: 20Yes	of contributing to the reaction, please indicate the appropriate category below: Color Additive (please specify) t (Please see attached sheet) submit a quality copy along with this questionnaire: XDYes DNo DUnknown DNo DUnknown EA-DO as CR#97-790-066 (copy attached) Outcome Attributed to Adverse Events
DAspartame DMonosodium Glutamate DSulfite MaHuang Extrac DUnknown Is the product label available, if yes Product Sample Available: Xi Yes Sample submitted to S	of contributing to the reaction, please indicate the appropriate category below: Color Additive (please specify) t (Please see attached sheet) submit a quality copy along with this questionnaire: XDYes DNo DUnknown DNo DUnknown EA-DO as CR#97-790-066 (copy attached)
DAspartame DMonosodium Glutamate DSulfite MaHuang Extrac DUnknown Is the product label available, if yes Product Sample Available: Wyes Sample submitted to S Death: Wyes DNo	of contributing to the reaction, please indicate the appropriate category below: Color Additive (please specify) t (Please see attached sheet) submit a quality copy along with this questionnaire: XDYes DNo DUnknown DNo DUnknown EA-DO as CR#97-790-066 (copy attached) Outcome Attributed to Adverse Events
D'Aspartame UMonosodium Glutamate D'Sulfite GOther MaHuang Extrac D'Unknown Se the product label available, if yes Product Sample Available: A Yes Gample submitted to S Death: A Yes DNo Life-Threatening: CYCs DNo	of contributing to the reaction, please indicate the appropriate category below: Color Additive (please specify) t (Please see attached sheet) submit a quality copy along with this questionnaire: XOYes ONO DUnknown No DUnknown EA-DO as CR#97-790-066 (copy attached) Outcome Attributed to Adverse Event: (If yes, include pertinent medical records)
OAspartame OMonosodium Glutamate OSulfite SOther MaHuang Extrac OUnknown s the product label available, if yes Product Sample Available: XYes Cample submitted to S Death: XYes ONo Life-Threatening: XYes ONo Hospitalization: OYes ONo (if YI	of contributing to the reaction, please indicate the appropriate category below: Color Additive (please specify) t (Please see attached sheet) submit a quality copy along with this questionnaire: XDYes DNo DUnknown DNo DUnknown EA-DO as CR#97-790-066 (copy attached) Outcome Attributed to Adverse Events

Adverse Questionnaire (IOM Exhibit 910-D) - Additional Comments

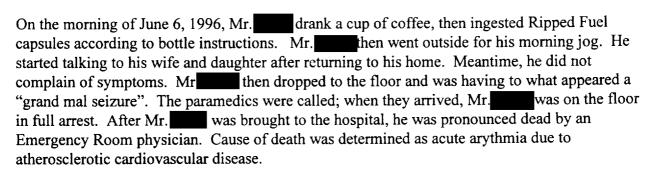
Complaint Number: CFSAN Project #12485

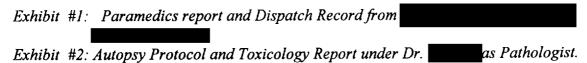
Investigator: Nianna M. Capalia

Date: August 28, 1997

Information on Adverse Reaction

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):		
The following information is what I learned from Mr	attorney for Ms.	
Ms. is widow to Mr. who died a	ifter ingesting TWINLAB®	
Metabolic Enhancer Ripped Fuel.		





How long did the symptoms last?

We do not know the answer to this question, since Mr. did not complain until he fell to the floor, and then became unconscious until his death.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.)

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^{*}The following comments correspond to questions listed in the Adverse Questionnaire.

List all Medication(s), Dietary Supplements(s), Food(s), and other product(s) used at the
It is believed that no other medications or diet products (other than Ripped Fuel) were taken. Ms. believes that her husband was taking multi-vitamins at the time of his death; however it is not recalled which kind they were. Ms. advised, that as far as she knew, Mr. had never experienced adverse reactions to any other medications or food products.
Exhibit #3: Fax from Ms. Secretary to Mr. The fax addresses the question of whether Mr. took other medications, dietary supplements, foods, and other products near the time of death.
Medical Information
Give health care provider's name, address, and phone number: 1.
3. Dr regular attending physician.
What medical tests were performed and what were the results? See above Autopsy Protocol and Toxicology report under Exhibit #2.
Where there any preexisting condition(s)/treatment(s)? Yes, there were prexisting conditions:
1) There is mention of "history of heart problems." (See Autopsy Protocol, Exhibit #2, 1st paragraph, 4th line)
2) "According to the decedent's wife, the decedent had been treated for pneumonia a few times

and it was stated that he had some sort of "build up" around his heart" (Same Exhibit, all of 3rd

during the course of the year. Mr. was is not aware of any complaints, prior problems, or

, Mr.

look the product to assist him in losing 40-50 pounds

paragraph)

3) According to Mr.

mental health history.

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

The following information is provided on the label. The label is black in color with white and red print.

"TWINLAB® Metabolic Enhancer Ripped Fuel***Thermogenic Formula***60 capsules***"

RECOMMENDED USE: As a dietary supplement, take 2 capsules before morning workout on an empty stomach. Also, take 2 capsules before afternoon and evening meals. Do not exceed 6 capsules daily. Taking more than the recommended amount will not improve results and may cause adverse reactions listed in the warning below. Begin use with one-half of the recommended dose (one capsule three times per day) to assess your tolerance. For best results, use as part of a low fat diet and excercise program. Please note: Guarana extract contains caffeine and should not be taken by those wishing to eliminate caffeine from the diet.

WARNING: Do not use if you are pregnant or nursing or if you are at risk or are being treated for high blood pressure, heart, liver, thryroid or psychiatric disease, diabetes, pernicious anemia, nervousness, anxiety, depression, seizure disorder, stroke or difficulty in urination due to prostate enlargement. Consult your health care professional before use if you are taking an MAO inhibitor or any other prescription drug. Discontinue use and consult your health care professional if dizziness, sleeplessness, tremors, nervousness, headache, heart palpations or tingling sensations occur. NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18. KEEP OUT OF REACH OF CHILDREN.

Two Capsules Provide: Ma Huang Extract...334mg (standardized for 6% ephedrine)

Guarana Extract...910mg (standardized for 22% caffeine)

L-Carnitine...100mg

Chromium...200mcg (from Chromic Fuel® patented chromium

picolinate)

*No U.S. RDA established

WARNING: Diabetics may use only under a physician's supervision because this product contains chromium picolinate which may enhance insulin sensitivity.

Lot number seen on neck of bottle and not on label reads: "Lot #56491"

Exhibit #4: Photocopy of TWINLAB® Metabolic Enhancer Ripped Fuel taken at Mr.

office, by his secretary, Ms.

Exhibit #5: Mrs. receipt, listing 4/25/96 and as the supposed date and location she purchased the Ripped Fuel.

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

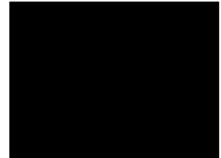
Other: MaHuang Extract.

The comments section for Dr. Autopsy Protocol (Exhibit #1) states: "Ephedrine is a stimulant medication, and as such may have contributed to a fatal arrhythmia in the decedent."

Other Exhibits

Exhibit #6: Copy of Original CFSAN Assignment

TRIAL LAWYERS



August 27, 1997

VIA FACSIMILE & U.S. MAIL

Nianna M. Capalia U.S. FOOD AND DRUG ADMINISTRATION 19900 MacArthur Blvd., Suite 300 Irvine, CA 92612

Re: v. Twin Laboratories, et al. Decedent:

Dear Ms. Capalia:

In follow-up to your meeting of August 25, 1997 with Mr.

enclosed please find a copy of the paramedic records of

We are also enclosing
a copy of a Visa statement showing the

purchase of 4/25/96. Mrs. will be further checking
her records to see if she has an actual store receipt for the
Ripped Fuel product, and we will forward that to you if she is
able to locate same.

In response to your other inquiries, Mrs. has advised that her husband was not taking any other medications or diet products (other than the Ripped Fuel), and she believes her husband was taking multi-vitamins at the time of his death; however, she does not recall what kind they were. She also advised that as far as she knew, he had never experienced adverse reactions to any medications or other food products.

If there is anything else you need at this time, please do not hesitate to give me a call.

Very truly yours,

Ву:___

Enclosures